Paper #16

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UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
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Alexandria, VA 22313-1450
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JAN 21 2005

Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Claudia Grillo

Dear Ms. Axelrad:

The attached application for patent term extension of U.S. Patent No. 5,656,667 was filed on January 7, 2005, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, OMACOR® (EPA ethyl ester and DHA ethyl ester) has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first approved commercial marketing or use. In this regard, please note the argument, on page 15 of the application, that "salt forms are included under the definition of a 'product' under 35 U.S.C. § 156(f)" (citing *Pfizer Inc. v. Dr. Reddy Labs., Ltd.*, 359 F.3d 1364-66, 69 USPQ2d 2016, 2018-2019 (Fed. Cir. 2004)). Applicant is understood to be arguing that the approved product is not the specific ester(s) approved, but includes the active moiety. Although applicant's interpretation of *Pfizer* is not shared by the undersigned (*Pfizer* is understood to have concluded that the approved product was amlodipine, not a specific salt of amlodipine, and to be limited to the facts therein), if applicant's interpretation is correct, then a prior approval of any drug product in the same active moiety under the same section of the Federal Food Drug and Cosmetic Act would bar patent term extension based upon a subsequent regulatory review of a drug product in that active moiety. See 35 U.S.C. 156(a)(5)(A). Accordingly, the assistance of your Office is requested in determining whether any product in the same active moiety of OMACOR® (EPA ethyl ester and DHE ethyl ester) has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before the approval of OMACOR® (EPA ethyl ester and DHE ethyl ester). In addition, the assistance of your Office is requesting in confirming that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7744 (telephone) or (571)273-7744 (facsimile).

Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Teresa Stanek Rea
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